NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 13. DEPARTMENT OF HEALTH SERVICES
HEALTH PROGRAMS SERVICES

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 111.) The Governor's Office authorized the notice to proceed through the rulemaking process on November 28, 2012.

[R13-225]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

R9-13-201	Amend
R9-13-202	Amend
R9-13-203	Amend
R9-13-204	Amend
R9-13-205	Amend
R9-13-206	Amend
R9-13-207	Amend
R9-13-208	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 36-132(A), 36-136(A)(7), and 36-136(F)

Implementing statutes: A.R.S. § 36-694, as amended by Laws 2012, Ch. 299, § 2

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 19 A.A.R. 154, February 1, 2013

4. The agency's contact person who can answer questions about the rulemaking:

Name: Ward Jacox, Office Chief

Address: Department of Health Services
Office of Newborn Screening
250 N. 17th Ave.
Phoenix, AZ 85007

Telephone: (602) 364-1410

Fax: (602) 364-1495

E-mail: Ward.Jacox@azdhs.gov

or

Name: Robert Lane, Acting Manager

Address: Department of Health Services
Office of Administrative Counsel and Rules
1740 W. Adams, Suite 203
Phoenix, AZ 85007

Telephone: (602) 542-1020
Fax: (602) 364-1150
E-mail: Robert.Lane@azdhs.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Arizona Revised Statutes (A.R.S.) § 36-694 contains requirements for ordering tests for certain congenital disorders and for reporting congenital disorder test results and hearing test results to the Department, and establishes a newborn screening program, a central database for information about newborns and infants who are tested for hearing loss or congenital disorders, an educational program and follow-up services, and a newborn screening program committee. Current rules in Arizona Administrative Code (A.A.C.) Title 9, Chapter 13, Article 2, specify the congenital disorders being tested for, the information required to be submitted when a bloodspot specimen is collected from a newborn or infant, the person responsible for collecting the specimen, when the specimen should be collected, reporting requirements for a bloodspot test, reporting requirements for hearing tests, and fees. Laws 2012, Ch. 299, § 2, removed the statutory fee cap for a second specimen for newborn screening from A.R.S. § 36-694 and allows the Department to establish a new fee for a second specimen through rulemaking. The Department is amending the newborn screening rules in 9 A.A.C. 13, Article 2, to increase the second fee to cover the costs associated with testing and follow-up for the disorders specified in the rules and billing for these activities. Laws 2008, Ch. 225, § 1, made the Arizona State Laboratory the "only testing facility for the program," removing the requirement for solicitation for testing by a contracted entity. In this rulemaking, the Department is also amending the rules to comply with Laws 2008, Ch. 225, and making other changes that clarify requirements in the rules to reduce the burden on stakeholders. The Department received an exception from the Governor's rulemaking moratorium, established by Executive Order 2012-03, for this rulemaking. The proposed amendments conform to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

7. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

Annual costs/revenues changes are designated as minimal when $5,000 or less, moderate when between $5,000 and $20,000, and substantial when $20,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification.

The Department will experience a significant benefit from specifying that the Arizona State Laboratory is the screening laboratory for bloodspot specimens and from clarifying other requirements in the rules. The Department will receive a substantial benefit from the fee increase for a second specimen. During FY 2013, the Department collected approximately $4,464,400 in fees to support the Newborn Screening Program. The Department was not able to collect an additional $1,047,568 due to unanticipated billing issues. To adequately provide bloodspot testing for 28 congenital disorders and follow-up for newborns and infants who had an abnormal screening test result for one of the 28 congenital disorders or hearing loss, as well as to bill for specimens submitted, the Department requires $7,306,000, a deficit of approximately $1,794,000. The Department anticipates that the fee increase for second specimens will provide sufficient funding to cover the deficit.

AHCCCS is expected to incur a substantial cost due to the fee increase for second specimens. According to CY 2012 birth data from the Department's *Health Status and Vital Statistics* publication, AHCCCS covers approximately 53.1% of births. According to figures received from AHCCCS, the cost impact from the fee increase for second specimens will range from $838,000 to $1.8 million.

Third-party payors, including private insurance plans, military health care facilities, Indian Health Service, and tribal health care facilities, paid for approximately 43.3% of births in Arizona in 2012, based on data from the Department's *Health Status and Vital Statistics* publication. Third-party payors are expected to incur a substantial cost due to the fee increase for second specimens; the cost incurred by a specific third-party payor would vary depending on the number of covered births.

Physicians and outpatient treatment centers order the collection of the majority of second specimens. A physician or an outpatient treatment center submitting a second specimen may be billed for the second specimen if the physician or outpatient treatment center does not provide the information specified in R9-13-203(C)(2)(b) or (c). Only a small percentage of second specimens submitted by physicians and outpatient treatment centers in FY 2013 were billed to these physicians or outpatient treatment centers. While, the Department anticipates that physicians and outpatient treatment centers, as a whole, may incur a substantial increase in costs due to the fee increase, an individual physician

or outpatient treatment center may incur minimal-to-substantial costs due to the fee increase for second specimens, depending on the number of second specimens for which they are billed.

Hospitals collect less than a third of second specimens and include information for billing on some of the specimens submitted. The Department anticipates that a hospital may incur minimal-to-substantial costs due to the fee increase for second specimens, depending on the number of second specimens submitted for which they are billed.

Midwives as a whole submit less than 300 second specimens per year. The additional costs incurred by a midwife for submitting a second specimen will vary with the number of the second specimens for which the midwife does not provide the information specified in R9-13-203(C)(2)(b) or (c), and may range from none-to-minimal, most of which may be reimbursed by parents.

Hospitals, audiologists, and others performing hearing tests report the results of both initial hearing screening tests and subsequent hearing screening or diagnostic tests. The Department anticipates that clarifying reporting requirements and removing some redundant requirements may provide a significant benefit to and are expected to impose at most a minimal burden on hospitals, audiologists, and others conducting hearing tests.

Parents paid for about 3.7% of births (percentage of self-paid births plus births for which the payor was unknown) in Arizona in 2012, according to data from the Department's 2012 *Health Status and Vital Statistics* publication. The cost to an individual parent for increased fees for second specimens is expected to be minimal. The Department anticipates that a parent of a baby with a third-party payor may incur minimal costs associated with an increase in insurance premiums if the third-party payor passes costs associated with the fee increase on to policyholders. The continuation of critical testing and follow-up activities is expected to provide a significant benefit to the parent of a baby tested through newborn screening or whose hearing test results are reported to the Department.

The Department expects to add three employees as a result of this rulemaking to replace employees who left since 2008. The addition of these employees does not require an increase in the Department's allocated FTEs.

9. The agency's contact person who can answer questions about the economic, small business, and consumer impact statement:

Name:	Ward Jacox, Office Chief
Address:	Department of Health Services Office of Newborn Screening 250 N. 17th Ave. Phoenix, AZ 85007
Telephone:	(602) 364-1410
Fax:	(602) 364-1495
E-mail:	Ward.Jacox@azdhs.gov
	or
Name:	Robert Lane, Acting Manager
Address:	Department of Health Services Office of Administrative Counsel and Rules 1740 W. Adams, Suite 203 Phoenix, AZ 85007
Telephone:	(602) 542-1020
Fax:	(602) 364-1150
E-mail:	Robert.Lane@azdhs.gov

10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceeding:

Date and time:	Wednesday, February 12, 2014, 1:00 p.m.
Location:	1740 W. Adams St., Conference Room 309 Phoenix, AZ 85007
Close of record:	Wednesday, February 12, 2014, 5:00 p.m.

A person may submit written comments on the proposed rules no later than the close of record to either of the individuals listed in items 4 and 9.

A person with a disability may request a reasonable accommodation, such as a sign language interpreter, by contact-

ing Robert Lane at Robert.Lane@azdhs.gov or (602) 542-1020. Requests should be made as early as possible to allow time to arrange the accommodation.

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rule does not require a permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No business competitiveness analysis was received by the Department.

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Not applicable

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 13. DEPARTMENT OF HEALTH SERVICES HEALTH PROGRAMS SERVICES

ARTICLE 2. NEWBORN AND INFANT SCREENING

Section

ARTICLE 2. NEWBORN AND INFANT SCREENING

R9-13-201. Definitions

In this Article, unless otherwise specified:

1. "Abnormal result" means an outcome that deviates from the range of values established by the Department for an analysis performed as part of a bloodspot test, or for a hearing test.
2. "Admitted" means the same as in A.A.C. R9-10-201.
3. "AHCCCS" means the Arizona Health Care Cost Containment System.
4. "Argininosuccinic acidemia" means a congenital disorder characterized by an inability to metabolize the amino acid Argininosuccinic acid due to defective argininosuccinate lyase activity.
5. "Arizona State Laboratory" means the entity operated according to A.R.S. § 36-251.

~~5.~~6. "Audiological equipment" means ~~instruments~~ an instrument used to help determine the presence, type, or degree of hearing loss by:

a. Providing ear-specific and frequency-specific stimuli to an individual; or
b. ~~measure a~~ Measuring an individual's physiological response to stimuli ~~determine the presence, type, or degree of hearing loss~~.

~~6.~~7. "Audiologist" means ~~an individual licensed under A.R.S. Title 36, Chapter 17~~ the same as in A.R.S. § 36-1901.

~~7.~~8. "Beta-ketothiolase deficiency~~"~~ means a congenital disorder characterized by an inability to metabolize 2-methyl-acetoacetyl-CoA due to defective mitochondrial acetoacetyl-CoA thiolase activity.

~~8.~~9. "Biotinidase deficiency" means a congenital disorder characterized by defective biotinidase activity that causes abnormal biotin metabolism.

~~9.~~10. ~~"~~Birth center" means a health care facility that is not a hospital and is organized for the sole purpose of delivering

newborns.

~~10.~~11. "Blood sample" means capillary or venous blood, but not cord blood, applied to the filter paper of a specimen collection kit.

~~11.~~12. "Bloodspot test" means multiple laboratory analyses performed on a blood sample to ~~detect~~ screen for the presence of congenital disorders listed in R9-13-202.

~~12.~~13. ~~"~~Carnitine uptake defect" means a congenital disorder characterized by a decrease in the amount of free carnitine due to defective sodium ion-dependent carnitine transporter OCTN2 activity.

~~13.~~14. "Citrullinemia" means a congenital disorder characterized by an inability to convert the amino acid citrulline and aspartic acid into argininosuccinic acid due to defective argininosuccinate synthetase activity.

~~14.~~15. "Classic galactosemia" means a congenital disorder characterized by abnormal galactose metabolism due to defective galactose-1-phosphate uridyltranferase activity.

~~15.~~16. "Congenital adrenal hyperplasia" means a congenital disorder characterized by decreased cortisol production and increased androgen production due to defective 21-hydroxylase activity.

~~16.~~17. "Congenital disorder" means an abnormal condition present at birth, as a result of heredity or environmental factors, that impairs normal physiological functioning of a human body.

~~17.~~18. "Congenital hypothyroidism" means a congenital disorder characterized by deficient thyroid hormone production.

~~18.~~19. "Cystic fibrosis" means a congenital disorder caused by defective functioning of a transmembrane regulator protein and characterized by damage to and dysfunction of various organs, such as the lungs, pancreas, and reproductive organs.

~~19.~~20. "Department" means the Arizona Department of Health Services.

~~20.~~21. "Discharge" means the termination of inpatient services to a newborn or an infant.

~~21.~~22. "Disorder" means a disease or medical condition that may be identified by a laboratory analysis.

~~22.~~23. "Document" means to establish and maintain information in written, photographic, electronic, or other permanent form.

~~23.~~24. "Educational materials" means printed or electronic information provided by the Department, explaining newborn and infant screening, any of the congenital disorders listed in R9-13-202, or hearing loss.

~~24.~~25. ~~"~~Electronic~~"~~ means the same as in A.R.S. § 44-7002.

~~25.~~26. "First specimen" means the initial specimen that is collected from a newborn who is less than five days of age and sent to the ~~screening laboratory~~ Arizona State Laboratory for testing and recording of demographic information.

~~26.~~27. "Glutaric acidemia type I" means a congenital disorder characterized by an accumulation of glutaric acid due to defective glutaryl-CoA dehydrogenase activity.

~~27.~~28. "Guardian" means an individual appointed by a court under A.R.S. Title 14, Chapter 5, Article 2.

~~28.~~29. "Health care facility" means a health care institution defined in A.R.S. § 36-401 where obstetrical care or newborn care is provided.

~~29.~~30. "Health care provider" means a physician, physician assistant, registered nurse practitioner, or midwife.

~~30.~~31. "Health-related services" means the same as in A.R.S. § 36-401.

~~31.~~32. "Hearing test" means an evaluation of ~~both ears of a newborn or infant~~ each of a newborn's or an infant's ears, using audiological equipment~~, for the presence, type, or degree of hearing loss~~ to:

a. Screen the newborn or infant for a possible hearing loss;
b. Determine that the newborn or infant does not have a hearing loss; or
c. Diagnose a hearing loss in the newborn or infant, including, if applicable, determining the type or degree of hearing loss.

~~32.~~33. "Hemoglobin S/Beta-thalassemia" means a sickle cell disease in which an individual has one sickle cell gene and one gene for beta thalassemia, another inherited hemoglobinopathy.

~~33.~~34. "Hemoglobin S/C disease" means a sickle cell disease in which an individual has one sickle cell gene and one gene for another inherited hemoglobinopathy called hemoglobin C.

~~34.~~35. "Hemoglobinopathy" means a congenital disorder characterized by abnormal production, structure, or functioning of hemoglobin.

~~35.~~36. "Home birth" means delivery of a newborn, outside a health care facility, when the newborn is not hospitalized within 72 hours of delivery.

~~36.~~37. ~~"~~Homocystinuria~~"~~ means a congenital disorder characterized by abnormal methionine and homocysteine metabolism due to defective cystathione-ß-synthase activity.

~~37.~~38. "Hospital" means the same as in A.A.C. R9-10-201.

~~38.~~39. "Hospital services~~"~~ means the same as in A.A.C. R9-10-201.

~~39.~~40. "3-Hydroxy-3-methylglutaric aciduria~~"~~ means a congenital disorder characterized by the accumulation of 3-hydroxy-3-methylglutaric acid due to a defective 3-hydroxy-3-methylglutaryl-CoA lyase activity.

~~40.~~41. "Identification code~~"~~ means a unique set of numbers or letters, or a unique set of both numbers and letters, assigned by the Department to a health care facility, a health care provider, an audiologist, or another person submitting specimen collection kits to the ~~screening laboratory~~ Arizona State Laboratory or hearing test results to the Department.

~~41.~~42. "Infant" means the same as in A.R.S. § 36-694.
~~42.~~43. "Inpatient" means an individual who:
a. Is admitted to a hospital,
b. Receives hospital services for 24 consecutive hours, or
c. Is admitted to a birth center.
~~43.~~44. "Inpatient services" means medical services, nursing services, or other health-related services provided to an inpatient in a health care facility.
~~44.~~45. "Isovaleric acidemia" means a congenital disorder characterized by an accumulation of isovaleric acid due to defective isovaleryl-CoA dehydrogenase activity.
~~45.~~46. "Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 16 carbon atoms in length due to defective long-chain 3-hydroxy acyl-CoA dehydrogenase activity.
~~46.~~47. "Maple syrup urine disease~~"~~ means a congenital disorder of branched chain amino acid metabolism due to defective branched chain-keto acid dehydrogenase activity.
~~47.~~48. "Medical services" means the same as in A.R.S. § 36-401.
~~48.~~49. "Medium chain acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 6 to 10 carbon atoms in length due to defective medium-chain acyl-CoA dehydrogenase activity.
~~49.~~50. "3-Methylcrotonyl-CoA carboxylase deficiency" means a congenital disorder characterized by an accumulation of 3-methylcrotonyl-glycine due to defective 3-methylcrotonyl-CoA carboxylase activity.
~~50.~~51. "Methylmalonic acidemia (Cbl A,B)" means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective activity of methylmalonyl-CoA racemase or adenosylcobalamin synthetase.
~~51.~~52. "Methylmalonic acidemia (mutase deficiency)" means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective methylmalonyl-CoA mutase activity.
~~52.~~53. "Midwife" means an individual licensed under A.R.S. Title 36, Chapter 6, Article 7, or certified under A.R.S. Title 32, Chapter 15.
~~53.~~54. "Multiple carboxylase deficiency" means a congenital disorder characterized by an inability to transport or metabolize biotin that leads to defective activity of propionyl-CoA carboxylase, beta-methylcrotonyl-CoA carboxylase, and pyruvate carboxylase.
~~54.~~55. "Newborn" means the same as in A.R.S. § 36-694.
~~55.~~56. "Newborn care" means medical services, nursing services, and health-related services provided to a newborn.
~~56.~~57. "Nursing services" means the same as in A.R.S. § 36-401.
~~57.~~58. "Obstetrical care" means medical services, nursing services, and health-related services provided to a woman throughout her pregnancy, labor, delivery, and postpartum.
~~58.~~59. "Organ" means a somewhat independent part of a human body, such as a salivary gland, kidney, or pancreas, which performs a specific function.
~~59.~~60. "Parent" means a natural, adoptive, or custodial mother or father of a newborn or an infant.
61. "Parenteral nutrition" means the feeding of an individual intravenously through the administration of a formula containing glucose, amino acids, lipids, vitamins, and minerals.
~~60.~~62. "Person" means the state, a municipality, district, or other political subdivision, a cooperative, institution, corporation, company, firm, partnership, individual, or other legal entity.
~~61.~~63. "Phenylketonuria" means a congenital disorder characterized by abnormal phenylalanine metabolism due to defective phenylalanine hydroxylase activity.
~~62.~~64. "Physician" means an individual licensed under A.R.S. Title 32, Chapters 13, 14, 17, or 29.
~~63.~~65. "Physician assistant" means an individual licensed under A.R.S. Title 32, Chapter 25.
~~64.~~66. "Propionic acidemia" means a congenital disorder characterized by an accumulation of glycine and 3-hydroxypropionic acid due to defective propionyl-CoA carboxylase activity.
~~65.~~67. "Registered nurse practitioner" means the same as in A.R.S. § 32-1601.
~~66. "Screening laboratory" means an entity contracted with the Department under A.R.S. § 36-694(I) to perform the bloodspot test~~.
~~67.~~68. "Second specimen" means a specimen that is sent to the ~~screening laboratory~~ Arizona State Laboratory for testing and recording of demographic information, after being collected:
a. From a newborn after a first specimen; or
b. From an individual at least five days and not older than one year of age, regardless of whether a first specimen was collected.
~~68.~~69. "Sickle cell anemia" means a sickle cell disease in which an individual has two sickle cell genes.
~~69.~~70. "Sickle cell disease" means a hemoglobinopathy characterized by an abnormally shaped red blood cell resulting from the abnormal structure of the protein hemoglobin.
~~70.~~71. "Sickle cell gene" means a unit of inheritance that is involved in producing an abnormal type of the protein hemo-

globin, in which the amino acid valine is substituted for the amino acid glutamic acid at a specific location in the hemoglobin.

~~71.~~72. "Specimen" means a blood sample obtained from and demographic information about a newborn or an infant.

~~72.~~73. "Specimen collection kit" means a strip of filter paper for collecting a blood sample attached to a form for obtaining the information specified in R9-13-203(A)(3) about a newborn or an infant.

~~73. "Test" means a laboratory analysis performed on body fluid, tissue, or excretion to determine the presence or absence of a disorder.~~

74. "Transfer" means a health care facility discharging a newborn and sending the newborn to a hospital for inpatient medical services without the intent that the patient will be returned to the sending health care facility.

75. "Transfusion" means the infusion of blood or blood products into the body of an individual.

76. "Trifunctional protein deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 18 carbon atoms in length due to defective mitochondrial trifunctional protein activity.

77. "Tyrosinemia type I" means a congenital disorder characterized by an accumulation of the amino acid tyrosine due to defective fumarylacetoacetate hydrolase activity.

78. "Verify" means to confirm by obtaining information through a source such as the newborn screening program, a health care provider, a health care facility, or a documented record.

79. "Very long-chain acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 14 to 18 carbon atoms in length due to defective very long-chain acyl-CoA dehydrogenase activity.

80. "Working day" means 8:00 a.m. through 5:00 p.m. Monday through Friday, excluding state holidays.

R9-13-202. Bloodspot Tests for Congenital Disorders

A bloodspot test shall ~~include laboratory analyses~~ screen for the following congenital disorders:

1. 3-Hydroxy-3-methylglutaric aciduria,
2. 3-Methylcrotonyl-CoA carboxylase deficiency,
~~1.~~3. Argininosuccinic acidemia,
4. Beta-ketothiolase deficiency,
~~2.~~5. Biotinidase deficiency,
6. Carnitine uptake defect,
~~3.~~7. Citrullinemia,
~~4.~~8. Classic galactosemia,
~~5.~~9. Congenital adrenal hyperplasia,
~~6.~~10. Congenital hypothyroidism,
11. Cystic fibrosis,
12. Glutaric acidemia type I,
~~7.~~13. Hemoglobin S/Beta-thalassemia,
~~8.~~14. Hemoglobin S/C disease,
~~9.~~15. Homocystinuria,
16. Isovaleric acidemia,
17. Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency,
~~10.~~18. Maple syrup urine disease,
19. Medium chain acyl-CoA dehydrogenase deficiency,
20. Methylmalonic acidemia (Cbl A,B),
21. Methylmalonic acidemia (mutase deficiency),
22. Multiple carboxylase deficiency,
~~11.~~23. Phenylketonuria,
24. Propionic acidemia,
~~12.~~25. Sickle cell anemia,
26. Trifunctional protein deficiency,
~~13.~~27. Tyrosinemia type I, and
28. Very long-chain acyl-CoA dehydrogenase deficiency.

~~14. 3-Methylcrotonyl-CoA carboxylase deficiency,~~
~~15. 3-Hydroxy-3-methylglutaric aciduria,~~
~~16. Beta-ketothiolase deficiency,~~
~~17. Carnitine uptake defect,~~
~~18. Glutaric acidemia type I,~~
~~19. Isovaleric acidemia,~~
~~20. Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency,~~
~~21. Medium chain acyl-CoA dehydrogenase deficiency,~~

~~22. Methylmalonic acidemia (Cbl A,B),~~
~~23. Methylmalonic acidemia (mutase deficiency),~~
~~24. Multiple carboxylase deficiency,~~
~~25. Propionic acidemia,~~
~~26. Trifunctional protein deficiency,~~
~~27. Very long-chain acyl-CoA dehydrogenase deficiency, and~~
~~28. Cystic fibrosis.~~

R9-13-203. General Requirements for Newborn and Infant Bloodspot Tests

A. When a bloodspot test is ordered for a newborn or an infant, a health care facility's designee, a health care provider, or the health care provider's designee shall:
1. Only use a specimen collection kit supplied by the Department;
2. Collect a blood sample from the newborn or infant on a specimen collection kit;
3. Complete the following information on the specimen collection kit:
   a. The newborn's or infant's name, gender, race, ethnicity, medical record number, and, if applicable, AHCCCS identification number;
   b. The newborn's or infant's type of food or food source;
   c. Whether the newborn or infant is from a single or multiple birth;
   d. If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;
   e. Whether the newborn or infant has a medical condition that may affect the bloodspot test results;
   f. Whether the newborn or infant received ~~antibiotics or~~ a blood transfusion and, if applicable, the date of the last blood transfusion;
   ~~g. The method of blood sample collection;~~
   ~~h.~~g. The date and time of birth, and the newborn's or infant's weight at birth;
   ~~i.~~h. The date and time of blood sample collection, and the newborn's or infant's weight when the blood sample is collected;
   ~~j.~~i. The ~~name and~~ identification code or the name and address of the health care facility or health care provider submitting the specimen collection kit;
   ~~k.~~j. The name, ~~identification code, and~~ address, and telephone number or the identification code of the health care provider responsible for the management of medical services provided to the newborn or infant;
   ~~l.~~k. Except as provided in subsection ~~(A)(3)(m)~~ (A)(3)(l), the mother's first and last names, date of birth, name before first marriage, mailing address, ~~phone~~ telephone number, and if applicable, AHCCCS identification number; and
   ~~m.~~l. If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn or infant; and
4. Submit the specimen collection kit to the ~~screening laboratory~~ Arizona State Laboratory no later than 24 hours or the next working day after the blood sample is collected.

B. A health care facility or a health care provider submitting a first specimen to the ~~screening laboratory~~ Arizona State Laboratory shall pay the Department the fee in R9-13-208(A).

C. A person who submits a second specimen to the ~~screening laboratory~~ Arizona State Laboratory shall:
1. Pay the fee in R9-13-208(B) to the Department, or
2. Provide the following information to the ~~screening laboratory~~ Arizona State Laboratory for billing purposes:
   a. The name, mailing address, and ~~phone~~ telephone number of the newborn's or infant's parent or the individual responsible for paying, if not the parent; and
   b. If the individual responsible for paying has health care insurance for the newborn or infant, information about the health care insurance, including:
      i. The policyholder's name;
      ii. The name and billing address of the health care insurance company;
      iii. The member identification number;
      iv. The group number, if applicable; and
      v. The effective date of the health care insurance; or
   c. That the individual responsible for paying has no health care insurance for the newborn or infant.

D. When a health care insurance company or an individual responsible for paying is identified as specified in subsection (C)(2), the health care insurance company or the individual responsible for paying shall pay the Department the fee in R9-13-208(B).

~~**E.** The screening laboratory shall perform a bloodspot test on a blood sample from a specimen collection kit if:~~
~~1. The blood sample on the specimen collection kit:~~
~~a. Contains a sufficient quantity of blood to complete the bloodspot test,~~
~~b. Is not clotted or layered,~~

~~c. Does not have serum rings,~~
~~d. Is not diluted or discolored,~~
~~e. Will elute from the filter paper,~~
~~f. Has not been applied to both sides of the filter paper, and~~
~~g. Is not contaminated;~~
~~2. The filter paper on the specimen collection kit is not contaminated, scratched, or abraded;~~
~~3. The information on the specimen collection kit is sufficient to identify:~~
~~a. The newborn or infant, and~~
~~b. The person who ordered the bloodspot test or caused the bloodspot test to be ordered; and~~
~~4. The screening laboratory receives the specimen collection kit within 14 days after the blood sample is collected.~~

~~F.~~**E.** When a home birth not attended by a health care provider is reported to a local registrar, a deputy local registrar, or the state registrar under A.R.S. § 36-333:
1. The local registrar, deputy local registrar, or state registrar shall notify the local health department of the county where the birth occurred; and
2. The local health department's designee shall collect a specimen from the newborn or infant according to the requirements in R9-13-204(A)(2) or R9-13-205(C).

~~G.~~**F.** A health care facility's designee, a health care provider, or the health care provider's designee shall ensure that:
1. Educational materials are provided to the parent or guardian of a newborn or an infant for whom a bloodspot test is ordered, and
2. The newborn's or infant's parent or guardian is informed of the requirement for a second specimen if the second specimen has not been collected.

~~H.~~**G.** For a home birth, a health care provider or the health care provider's designee shall provide educational materials to the parent or guardian of a newborn or an infant for whom a bloodspot test is ordered.

R9-13-204. First Specimen Collection

A. When a newborn is born in a hospital, the hospital's designee shall collect a first specimen from the newborn according to whichever of the following occurs first:
1. Unless specified otherwise by a physician, physician assistant, or registered nurse practitioner, ~~Before~~ before administering a transfusion~~, unless specified otherwise by a physician, physician assistant, or registered nurse practitioner~~ or parenteral nutrition;
2. When the newborn is at least 24 but not more than 72 hours old; or
3. Before the newborn is discharged, unless the newborn:
   a. Is transferred to another hospital before the newborn is 48 hours old; or
   b. Dies before the newborn is 72 hours old.

B. If a newborn is admitted or transferred to a hospital before the newborn is 48 hours old, the receiving hospital's designee shall:
1. Verify that the first specimen was collected before admission or transfer, or
2. Collect a first specimen from the newborn according to the requirements in subsection (A).

C. When a newborn is born in a birth center, the birth center's designee shall collect a first specimen from the newborn according to subsections (A)(1) or (A)(2).

D. For a home birth attended by a health care provider, the health care provider or the health care provider's designee shall collect a first specimen from the newborn according the requirements in subsection (A)(2).

R9-13-205. Second Specimen Collection

A. After a newborn's or an infant's discharge from a health care facility or after a home birth, a health care provider or the health care provider's designee shall:
1. Collect a second specimen from ~~a~~ the newborn or infant not older than one year of age~~:~~
   ~~a. When the newborn is at least 5 but not more than 10 days old; or~~
   ~~b.~~ ~~At~~ at the time of ~~a~~ the newborn's or infant's first visit to the health care provider~~;~~, or
2. Verify that a health care facility or different health care provider has collected ~~the~~ a second specimen from the newborn or infant.

B. If a newborn is an inpatient of a health care facility at 5 days of age, the health care facility's designee shall collect a second specimen from the newborn:
1. When the newborn is at least 5 but not more than 10 days old; or
2. If the newborn is discharged from the health care facility when the newborn is at least 5 but not more than 10 days old, before discharge.

C. For a home birth that is not attended by a health care provider, a local health department's designee shall collect a specimen from a newborn or an infant if the local health department's designee has not verified that a second specimen has ~~not~~ already been collected from the newborn or infant.

~~**D.** A health care provider or the health care provider's designee shall ensure that a subsequent specimen is ordered for a newborn or child one year of age or less, according to the requirements in R9-13-203, when the health care provider or the health care provider's designee:~~
~~1. Begins providing health care to the newborn or child, and~~
~~2. Cannot verify the results of a bloodspot test that was conducted on a second specimen from the newborn or child.~~

R9-13-206. Reporting Requirements for Specimens

~~**A.** The screening laboratory shall:~~
~~1. Report in written or electronic format:~~
~~a. The results of a bloodspot test on a specimen; and~~
~~b. For a specimen that does not meet the requirements for testing specified in R9-13-203(E):~~
~~i. That the bloodspot test was not performed on the specimen; and~~
~~ii. The reason the bloodspot test was not performed; and~~
~~2. Send the report to:~~
~~a. The health care provider identified on the specimen collection kit;~~
~~b. If applicable, the health care facility identified on the specimen collection kit; and~~
~~c. The Department.~~
~~**B.** The screening laboratory shall begin reporting bloodspot test results for the congenital disorders specified in:~~
~~1. R9-13-202 (1) through (13), on the effective date of these rules;~~
~~2. R9-13-202(14) through (27), no later than August 31, 2006; and~~
~~3. R9-13-202(28), no later than June 30, 2007.~~

A. The Arizona State Laboratory shall report, in written or electronic format, to the health care provider and, if applicable, health care facility identified on a specimen collection kit:
1. The results of a bloodspot test on a specimen; or
2. For a specimen that does not meet quality standards established by the Arizona State Laboratory in compliance with 42 CFR 493.1200:
   a. That a bloodspot test was not performed on the specimen; and
   b. The reason the bloodspot test was not performed.

~~**C.**~~**B.** A health care facility's designee, a health care provider, or the health care provider's designee, who orders a subsequent test on a newborn or an infant in response to an abnormal result on a bloodspot test, shall send the results of the subsequent test in writing to the Department, if the subsequent test is not performed by the ~~screening laboratory~~ Arizona State Laboratory.

~~**D.**~~**C.** Bloodspot test results are confidential subject to the disclosure provisions of 9 A.A.C. 1, Article 3, and A.R.S. §§ 12-2801 and 12-2802.

R9-13-207. Reporting Requirements for Hearing Test Results

A. When an initial hearing test is performed on a newborn, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:
1. The newborn's name, date of birth, gender, and medical record number;
2. Whether the newborn is from a single or multiple birth;
3. If the newborn is from a multiple birth, the birth order of the newborn;
4. The ~~newborn's mother's~~ first and last names and date of birth of the newborn's mother;
~~5. The name and identification code of the health care facility or health care provider submitting the hearing test results;~~
~~6.~~5. The name and identification code of the health care facility of birth;
6. If the initial hearing test was not performed by the health care facility of birth, either:
   a. The name and identification code of the health care facility where the initial hearing test was performed, or
   b. The name and telephone number of the health care provider who performed the initial hearing test;
7. The name of the health care provider responsible for the coordination of medical services for the newborn;
8. The date of the hearing test;
9. Whether or not the hearing test was performed when the newborn was an inpatient;
10. The audiological equipment used for the hearing test and the type of hearing test performed;
11. The hearing test result for each of the newborn's ears; and
12. The name, address, and ~~phone~~ telephone number of the contact person for the health care facility or health care provider.

B. In addition to the information in subsection (A), if the reported results of an initial hearing test on a newborn include an abnormal result, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:
1. The newborn's race, ethnicity, and if applicable, AHCCCS identification number;
2. Except as provided in subsection (B)(3), the mother's ~~date of birth,~~ name before first marriage, mailing address, and

~~phone~~ telephone number;

3. If the newborn's mother does not have physical custody of the newborn, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn;
4. The name of the health care provider who will be responsible for the coordination of medical services for the newborn after the newborn is discharged from the health care facility, if different from the health care provider specified in subsection (A)(7); and
5. The name and ~~phone~~ telephone number of the person to whom the newborn's mother or other person who has physical custody of the newborn was referred for a subsequent hearing test.

C. When a hearing test is performed on a newborn or an infant after an initial hearing test, the designee of the health care facility, health care provider, or other person that performs the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following information:

1. The newborn's or infant's name, date of birth, and gender;
2. Whether the newborn or infant is from a single or multiple birth;
3. If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;
4. The ~~newborn's mother's~~ first and last names and date of birth of the newborn's or infant's mother;
5. ~~The name of the health care facility where the initial hearing test was performed, or the name and address of the health care provider who performed the initial hearing test;~~
6. ~~6.~~5. The name of the health care facility of birth;
6. If the initial hearing test was not performed by the health care facility of birth, either:
   a. The name of the health care facility where the initial hearing test was performed, or
   b. The name and telephone number of the health care provider who performed the initial hearing test;
7. The name, telephone number, and identification code of the person submitting the subsequent hearing test results;
8. The date of the subsequent hearing test;
9. The audiological equipment used for the subsequent hearing test; ~~and the~~
10. The type of hearing test performed;
11. ~~10.~~The result, including a quantitative result if applicable, for each of the newborn's or infant's ears on the subsequent hearing test; ~~and~~
12. If the subsequent hearing test was performed by an audiologist or a physician to determine that the newborn or infant does not have a hearing loss or diagnose a hearing loss in the newborn or infant:
    a. Whether the newborn or infant has a hearing loss and, if so, the type and degree of hearing loss; and
    b. A copy of the narrative that describes the hearing test performed on the newborn or infant to determine that the newborn or infant does not have a hearing loss or diagnose a hearing loss in the newborn or infant, the results of the hearing test, and the analysis of the hearing test results by the audiologist or physician who performed the hearing test; and
13. ~~11.~~The name, address, and ~~phone~~ telephone number of the contact person for the health care facility, health care provider, or other person that performed the subsequent hearing test, if different from the person specified in subsection (C)(7).

D. In addition to the information in subsection (C), if the reported results of a subsequent hearing test on a newborn or an infant include an abnormal result, the person submitting the report on the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following ~~information~~:

1. Except as provided in subsection (D)(2), the ~~newborn's or infant's mother's mailing address and phone number~~ mailing address and telephone number of the newborn's or infant's mother;
2. If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn or infant;
3. The name of the health care provider who is responsible for the coordination of medical services for the newborn or infant; and
4. If applicable, the name and ~~phone~~ telephone number of the person to whom the newborn's or infant's parent was referred for further hearing tests, evaluation services, specialty care, or early intervention.

E. A health care facility's designee, health care provider, health care provider's designee, or other person required to report under subsections (A), (B), (C), or (D) shall submit, in an electronic format specified by the Department, the information specified in subsections (A), (B), (C), or (D) for hearing tests performed each week by the sixth day of the subsequent week.

R9-13-208. Fees

A. The fee for a first specimen is $30.00.

B. The fee for a second specimen is ~~$40.00~~ $65.00.